PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	22 MAR 2005
Applicant's or agent's file reference 27798	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/IL04/00395	10 May 2004 (10.05.2004)	12 May 2003 (12.05.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 5/02 and US Cl.: 600/504-507

Applicant

CHEETAH MEDICAL INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [X] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sharon A. Greene for Max Hindenburg Telephone No. (708) 308-0858

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL04/00395

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL04/00395

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL04/00395

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 64 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: on line 1 of claim 64, "said plurality of its" should be replaced with "said plurality of its electrodes".

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 2-4,6,7,10-14,24-26,35-37,39-43,47-49,51,52,54-58,60,66,68-70,73,74
The opinion as to Novelty was negative (No) with respect to claims 1,5,8,9,15-23,27-34,38,44-46,50,53,59,61-65,67,71,72
The opinion as to Inventive Step was positive (Yes)with respect to claims 2,3,6,7,10-14,24-26,35,36,39-43,47,48,51,52,55-58,60,68-70
The opinion as to Inventive Step was negative(NO) with respect to claims 1,4,5,8,9,15-23,27-34,37,38,44-46,49,50,53,54,59,61-67,71-74
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-74
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:
Claims 1, 5, 8, 9, 15-22, 27-34, 38, 44-46, 50, 53, 59, 61-65, 67, 71, and 72 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 6,015,393 to Hovland et al. Hovland discloses a system for measuring blood flow in an organ of a subject. The system comprises a radiofrequency generator for generating output radiofrequency signals (col. col. 9, lines 35-44 of Hovland), wherein radio frequency is defined as frequencies in the range of 3 kiloHertz to 300,000 megaHertz. A plurality of electrodes 30 (figs. 1 & 2 of Hovland) are designed to be connectable to the skin of the subject (col. 9, lines 35-37; col. 10, lines 17-19 of Hovland) and capable of transmitting output radiofrequency signals to the organ and sensing input radiofrequency signals from the organ (col. 9, lines 35-40; col. 9, line 61-col. 10, line 6; col. 11, lines 7-14 of Hovland). The data processing device 50 constitutes a mixer, electrically communicating with the generator and at least a portion of the electrodes and capable of mixing the output radiofrequency signal and the input radiofrequency signals, so as to provide a mixed radiofrequency signal being indicative of blood flow (fig. 1; col. 11, lines 6-15 of Hovland). Electronic circuitry filters out a portion of the mixed radiofrequency signal (figs. 22; col. 14, lines 13-17 of Hovland).

While Hovland fails to explicitly point out a radiofrequency generator, the applicants should note that since a radio frequency signal is generated through electrodes 30 (col. 9, lines 61-67 of Hovland), a radio frequency generator must inherently be included in the system, as electrodes themselves are incapable of generating such a signal and some source must be present for the provided signal.

As to the language "to substantially increase a signal-to-noise ratio of a remaining portion of said mixed radiofrequency signal" on the final lines of each of claim 1 and claim 34, and similarly the language in claims 29, 30, 44, and 45, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over Hovland, since the reference discloses all of the claimed elements and their recited relationships. The circuitry disclosed by Hovland is certainly capable of increasing a signal-to-noise ratio, and, indeed, the function of a lowpass filter, as shown in figure 22 of Hovland, is often to increase such a ratio. Furthermore, and particularly with regard to claims 46, 50, 53, 54, 59, 61-63, 65, 66, 67, 71 and 72, the applicants should note that the term "increase" is a relative term. Since the applicants have not provided a reference point for the term "increase", the broadest reasonable interpretation of the term leads to an interpretation in which the ratio is increased compared to any other signal. Given such an interpretation, a signal employing a low pass filter would most certainly result in an increased signal-to-noise ratio compared to a signal riddled with other noise.

Regarding claims 5, 38, and 50 a digitizer (A/D converter) digitizes the remaining portion of the signal (fig. 22; col. 10, lines 50-55 of Hovland).

Regarding claims 8 and 53, a data processor calculates at least one quantity using the signal, the quantity being an artery blood flow rate (col. 10, lines 40-49 of Hovland).

As to the types of blood flow rate recited in claim 9, the applicants should further note that this is also merely "intended use" language, wherein blood flow type depends merely upon a selection of a particular portion of the body on which to place the electrodes. Similarly, in claims 21 and 32, the external organ about which the conducting material may wind is also merely a matter of intended use. This intended use language cannot be relied upon to define over Hovland since the reference discloses all of the

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In case the space in any of the preceding boxes is not sufficient.

claimed elements and their recited relationships. The electrodes of Hovland are certainly capable of being used in a number of different locations on a patient, such as on a wrist to obtain radial blood flow rate information. Also, the electrodes of Hovland are capable of being wrapped around an arm, leg, or foot, particularly in the case where the user is a baby.

Regarding claims 15-17, 59, and 61-63, the plurality of electrodes may range from two to five electrodes (figs. 1-3; col. 9, lines 34-39; col. 9, line 61-col. 10, line 6; col. 13, line 48-col. 14, line 8 of Hovland).

Regarding claims 18 and 64, the electrodes are designed and constructed to have a substantial constant sensitivity to electrical signal transmitted through the electrodes, irrespective of an orientation of the electrodes on the subject (figs. 1 and 2 of Hovland).

Regarding claims 19, 31-33, and 65 at least a portion of the plurality of electrodes comprises at least one elongated conducting material constructed and designed to wind at least a portion of an external organ of the subject, so as to have a substantial constant sensitivity to electrical signals transmitted through said electrodes, irrespective of an orientation of the electrodes on the organ (fig. 2 of Hovland).

Regarding claims 20 and 33, a portion of the electrodes comprises an attaching material (col. 10, lines 17-19 of Hovland).

Regarding claims 22 and 67, a bioimpedance detector electrically communicates with at least a portion of the electrodes for detecting a voltage between a first location and a second location of the subject and generates said input radio frequency signals in response to the voltage, the signals being indicative of the impedance of the organ (col. 11, lines 7-15 of Hovland).

Regarding claims 27 and 71, a display 64 is included for displaying the blood flow (col. 10, lines 58-64 of Hovland).

Regarding claims 28 and 72, the display 64 is capable of displaying blood flow as a function of time (figs. 4-6; col. 12, lines 1-11 of Hovland).

Claims 31-33 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 4,094,309 to Grzenia. Grzenia discloses an electrode for transmitting and receiving signals (EKG) of an internal organ of a subject (col. 2, lines 32-43 of Grzenia), comprising at least one elongated conducting material 12 constructed and designed to wind about at least a portion of an external organ of the subject (fig.5 of Grzenia), so as to have a substantial constant sensitivity to the signals, irrespective of an orientation of the electrode on the external organ.

Regarding claim 32, the external organ is an arm (fig. 5 of Grzenia).

Regarding claim 33, an attaching material 16 is provided for attaching an EKG lead (col. 2, lines 38-43 of Grzenia).

Claims 4, 37, and 49 lack an inventive step under PCT Article 33(3) as being obvious over Hovland, as applied to claims 1, 5, 8, 9, 15-22, 27-34, 38, 44-46, 50, 53, 59, 61-65, 67, 71, and 72 above, in view of US Patent No. 6,015,393 to Govari. Hovland fails to disclose the electronic circuitry comprising an analog amplification circuit. However, Govari teaches a system for measuring blood flow in an organ of a subject comprising a radio frequency generator 58, a plurality of electrodes 28, 30, and electronic circuitry, which circuitry includes an amplification circuit 52 (col. 12, lines 32-48 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Govari with that of Hovland in order to more accurately process the acquired signal.

Claim 54 lacks an inventive step under PCT Article 33(3) as being obvious over Hovland, as applied to claims 1, 5, 8, 9, 15-22, 27-34, 38, 44-46, 50, 53, 59, 61-65, 67, 71, and 72 above. Hovland lacks determining any of the particular blood flow rates listed in claim 54 (external carotid, internal carotid, ulnar, etc.) However, the applicants have not disclosed that the particular type of blood flow solves a stated problem or is for any particular purpose. Moreove, it appears that the method would perform equally well with any type of blood flow being determined. Accordingly the use of any of the listed blood flow types in claim 54 is deemed to be a design consideration which fails to patentably distinguish over Hovland.

Claim 66 lacks an inventive step under PCT Article 33(3) as being obvious over Hovland, as applied to claims 1, 5, 8, 9, 15-22, 27-34, 38, 44-46, 50, 53, 59, 61-65, 67, 71, and 72 above. Hovland lacks determining the blood flow of any of the selected organs recited in group 66 in claim 54 (chest, hip, thigh, etc.) However, the applicants have not disclosed that the particular of type of blood flow solves a stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with any type of blood flow being determined. Accordingly the use of any of the particular blood flow types listed in claim 66 is deemed to be a design consideration which fails to patentably distinguish over Hovland.

Claims 73 and 74 lack an inventive step under PCT Article 33(3) as being obvious over Hovland, as applied to claims 1, 5, 8, 9, 15-22, 27-34, 38, 44-46, 50, 53, 59, 61-65, 67, 71, and 72 above. Hovland lacks the signal-to-noise ratio being increased by at least 10 dB or at least 20dB However, the applicants have not disclosed that the particular level of increase in signal-to-noise ratio solves a stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with so long as the ratio is increased at all. Accordingly the use the ratio being increased to either 10 dB or 20dB is deemed to be a design consideration which fails to patentably distinguish over Hovland.

Claims 2, 3, 35, 36, 47, and 48 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system, apparatus, or method for measuring blood flow wherein the mixer that is operable to provide both a radiofrequency sum and a radiofrequency difference, along with all of the other limitations of the claims.

Claims 6, 7, 39, 40, 51, and 52 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly

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In case the space in any of the preceding boxes is not sufficient.

suggest a system, apparatus, or method for measuring blood flow wherein the electronic circuitry is designed and constructed so as to minimize sensitivity of the input radiofrequency signals to impedance differences between said plurality of electrodes and the organ of the subject, along with all of the other limitations of the claims.

Claims 10-14 and 55-58 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system or method for measuring blood flow wherein the data processor is programmed to electronically control a pacemaker, drug administrating device, or cardiac assist device in accordance with a value of said at least one quantity, along with all of the other limitations of the claims.

Claims 24-26, 41-43, and 68-70 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system, apparatus, or method for measuring blood flow, wherein the electronic circuitry comprises a differentiator for performing at least one time-differentiation, or a step of time-differentiation is performed, to provide a respective derivative of said impedance between the first and second locations, along with all of the other limitations of the claims.

Claim 60 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for measuring blood flow, whereina number of said plurality of electrodes is selected so as to substantially decouple the input radiofrequency signals from at least one effect selected from the group consisting of a posture changes effect, a respiration effect, and a motion effect.

Claims 1-74 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.